

- 1) Claims 5 and 6 are rejected under 35 U.S.C. §112, first paragraph;
- 2) Claims 5 and 6 are rejected under 35 U.S.C. §112, second paragraph; and
- 3) Claims 1-4 and 7 are rejected under 35 U.S.C. §103(a), as allegedly obvious over Cook et al. (U.S. Pat. No. 5,554,646) in view of applicants' disclosure at page 11, line 13-25, Cain et al. (WO 97/18320), Chin et al. and Baltes et al. (U.S. Pat. No. 3,162,658).

Applicants believe that the present amendments and the following remarks traverse the Examiner's rejection of the claims.

### REMARKS

#### 1. The Claims are Definite

Claims 5 and 6 stand rejected under 35 U.S.C. §112, first paragraph. Applicants have amended Claims 5 and 6 to specify that the alkyl esters are octadecadienoic acid alkyl esters. Support for this amendment is found at multiple places in the specification. Applicant respectfully submits that the Claims are now definite.

#### 2. The Claims are Enabled

Claims 5 and 6 stand rejected under 35 U.S.C. §112, first paragraph. Applicants have amended Claims 5 and 6 to specify that the alkyl esters are octadecadienoic acid alkyl esters. Support for this amendment is found at multiple places in the specification. Applicant respectfully submits that the Claims are enabled.

#### 3. The Claims are not Obvious

The claims 1-4 and 7 stand rejected under 35 U.S.C. §103(a), as allegedly obvious over Cook et al. (U.S. Pat. No. 5,554,646) in view of applicants' disclosure at page 11, line 13-25, Cain et al. (WO 97/18320), Chin et al. and Baltes et al. (U.S. Pat. No. 3,162,658).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (MPEP § 2143). Failure to establish **any one** of these three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles Applicant to

allowance of the claims in issue.<sup>3</sup> The Examiner has failed to provide references that teach each element of the claims and has failed to provide references that provide a reasonable expectation of success.

With respect to the Cook patent (U.S. Pat. No. 5,554,646), the Examiner states:

However, since the preferred amounts of the regio isomers 8,10- and an [sic] 11,13-octadecadienoic acid derivative in the claimed invention are limited to less than 2 percent, this amount includes zero percent of the regio isomers as disclosed by Cook. Thus, Cook' teachings meet this limitation.

Office Action, pg. 5. As detailed in the accompanying Declaration by Asgeir Sæbo, Applicants have conducted a repeat of the experimental conditions utilized by in the '646 patent. Analysis of the CLA composition resulting from the conjugations methods described in Column 2 of the '646 patent indicates that the compositions obtained by Cook contained approximately 1.58% c11,t13 CLA and 2.34% t9,t11 and t10,t12 CLA. (See paragraphs 4 and 5 of the Saebo Declaration). Therefore, even excluding the presence of the 8,10 isomer, the Cook CLA composition contained greater than 3.9% c11,t13 isomers and trans-trans isomers, which is almost double the claimed limitation of less than 2% 11,13; 8,10, and trans-trans isomers. Thus, Cook does not meet this claim limitation. The other cited references do not remedy this deficiency.

The Examiner further argues that the arguments presented in Mr. Sæbo 's previous Declaration are moot in view of the disclosure of Cain et al. (WO97/18320). Office Action, pg. 7. The Examiner states that:

The conjugated linoleic acid moieties [of Cain] are composed of 48.9% of c9,t11, 51.1% of t10,12c linoleic acid moieties. The analysis was carried out with gas chromatography and no other isomer of conjugated linoleic acid is detected. See, particularly, the example 18 at page 36.

Office Action, pg. 7-8. As detailed in the accompanying Declaration by Asgeir Sæbo, Applicants have conducted a repeat of the experimental conditions utilized by Cain et al. Analysis of the CLA composition resulting from the conjugations methods described in Example 6 of Cain et al. indicates that the compositions obtained by Cain et al. contained approximately 3.49% c11,t13 CLA and 2.24% t9,t11 and t10,t12 CLA. (See paragraphs 6 and 7 of the Saebo Declaration). Therefore, even excluding the presence of the 8,10 isomer, the Cain CLA composition contained

---

<sup>3</sup> See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

greater than 4.0% c11,t13 isomers and trans-trans isomers, which is more than double the claimed limitation of less than 2% 11,13; 8,10, and trans-trans isomers. Thus, Cain et al. does not meet this claim limitation. The other cited references do not remedy this deficiency.

Thus, none of the references, either alone or in combination, teach the claim limitation of conjugated linoleic acid alkyl compositions comprising less than 2% 8,10; 11,13; and trans-trans isomers. The Examiner's alleged prima facie case of obviousness thus stands rebutted because the references do not teach or suggest this claim limitation. Accordingly, the Claims should be passed to allowance.

Finally, the Examiner has requested evidence of the criticality, or unexpected benefit of CLA compositions containing less than 2% of 8,10; 11,13, and trans-trans octadecadienoic acid isomers. As detailed in paragraph 8 of the accompanying Sæbo Declaration, the Examiner's attention is again directed to the publication attached at Tab 3, Yurawecz et al., Variation in isomer distribution in commercially available conjugated linoleic acid, *Fett/Lipid* 101:277-282 (1999). This study, by researchers at the U.S. Food and Drug Administration (U.S.F.D.A.), was "undertaken to determine the content and distribution of CLA isomers in commercially available CLA capsules and liquid products with labels stating to contain CLA." In brief, the authors of the Yurawecz *et al.* publication note that:

While it has not been established, which isomer(s) is (are) responsible for the reported beneficial properties of CLA, it is generally thought that anticarcinogenicity is due to rumenic acid [c9,t11 octadecadienoic acid]. The nutritional and physiological effects, if any, of other CLA isomer(s) in commercially available CLA preparations are not known.

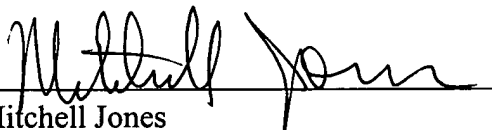
(Yurawecz, *p.* 280). In an additional reference cited within Yurawecz *et al.*, (published by members of the Yurawecz group) it was found that the 11 *cis*, 13 *trans*-18:2 isomer was found to was found to accumulate preferentially in heart phospholipids and specifically in heart and liver diphosphatidylglycerol (DPG) of pigs feed commercial CLA mixtures. Yurawecz *et al.* note that in response to their "findings that 11 *cis*, 13 *trans*-18:2 was selectively incorporated into DPG . . . , a major supplier of commercial CLA preparations recently modified [their production] process to eliminate the 11 *cis*, 13 *trans*-18:2 isomer." (Yurawecz, *p.* 281).

As can be seen, the different isomers of CLA have different accumulation rates and may have different activities. The use of isomers of unknown activity is therefore undesirable. Thus, as indicated by Mr. Sæbo in his Declaration, it is desirable to control the amounts of CLA isomers of unknown function in CLA compositions.

**Conclusion**

All grounds of rejection and objection of the Office Action of April 10, 2002 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: September 30, 2002

  
\_\_\_\_\_  
J. Mitchell Jones  
Registration No. 44,174

MEDLEN & CARROLL, LLP  
220 Montgomery Street, Suite 2200  
San Francisco, California 94104  
415.705.8410

**APPENDIX I**  
**MARKED-UP VERSION OF REWRITTEN, ADDED,**  
**AND/OR CANCELLED CLAIMS**

The following is a version of the claims pursuant to 37 C.F.R. §1.121 (c)(1)(ii) with markings showing changes made herein to the previous version of record of the claims.

**IN THE CLAIMS:**

Please amend the Claims as follows:

5. (Amended once) The ester composition of claim 4 wherein said c9,t11-[octadecanoic]octadecadienoic acid alkyl ester contained in said first composition part constitutes greater than 60 percent of the total isomers of [octadecanoic]octadecadienoic acid alkyl esters.
6. (Amended once) The ester composition of claim 4 wherein said t10,c12-[octadecanoic]octadecadienoic acid alkyl ester contained in said first composition part constitutes greater than 60 percent of the total isomers of [octadecanoic]octadecadienoic acid alkyl esters.
8. (Amended once) The [ester] food product of claim[s] 1[-7] wherein said conjugated linoleic acid alkyl esters [has]have an alkyl radical selected from the group consisting of methyl-, ethyl-, propyl-, isopropyl-, butyl-, and isobutyl-.

**- APPENDIX II -**  
**CLEAN VERSION OF THE ENTIRE SET OF PENDING CLAIMS AS  
AMENDED IN THIS COMMUNICATION**

1. (Amended twice) A food product comprising conjugated linoleic acid alkyl esters in a biologically active concentration, said alkyl esters comprising less than about two percent trans,trans; 8,10 and 11,13 octadecadienoic acid isomers.
2. (Amended once) The food product of claim 1 wherein the concentration of conjugated linoleic acid alkyl esters in said food product is about 0.05 to 3.5 percent by weight.
3. (Amended twice) The food product of claim 1 wherein said conjugated linoleic acid alkyl ester is comprised of at least 50 percent up to about 99 percent by weight of octadecadienoic acid alkyl ester isomers selected from the group consisting of c9,t11-octadecadienoic acid alkyl ester and t10,c12-octadecadienoic acid alkyl ester.
4. (Amended twice) A conjugated linoleic acid alkyl ester composition for safe use as a feed, food ingredient, or food supplement obtained by direct isomerization of an unrefined linoleic acid comprising
  - a composition of isomers in one part comprising at least 50 percent by weight of ester isomers selected from the group consisting of c9,t11- octadecadienoic acid alkyl ester and t10,c12-octadecadienoic acid alkyl ester, and combinations thereof, and
  - in a second part comprising less than two percent by aggregate weight of ester isomers selected from the group consisting of 8,10-octadecadienoic acid alkyl esters, 11,13-octadecadienoic acid alkyl esters, and trans,trans-octadecadienoic acid alkyl esters, and
  - in a third part comprising in the range of 0.1 to 0.5 percent phosphatidyl residue remaining after isomerization of said unrefined linoleic acid.
5. (Amended once) The ester composition of claim 4 wherein said c9,t11-octadecadienoic acid alkyl ester contained in said first composition part constitutes greater than 60 percent of the total isomers of octadecadienoic acid alkyl esters.
6. (Amended once) The ester composition of claim 4 wherein said t10,c12-octadecadienoic acid alkyl ester contained in said first composition part constitutes greater than 60 percent of the total isomers of octadecadienoic acid alkyl esters.

8. (Amended once) The food product of claim 1 wherein said conjugated linoleic acid alkyl esters have an alkyl radical selected from the group consisting of methyl-, ethyl-, propyl-, isopropyl-, butyl-, and isobutyl-.